

REMARKS

Status of Claims: Claim 46 is objected to, Claims 46-67 are rejected under the doctrine of obviousness type double patenting, Claims 48, 50, 51, 54, and 58-62 are rejected as anticipated, Claims 46-67 are rejected as obvious.

Claims 46, 48, 50, and 60 are presently amended, and Claims 52-53, 63-64 and 68-78 are cancelled without prejudice to Applicants' right to file a continuation application directed to one or more of the cancelled claims.

Claim 46 is amended to make the correction suggested by the Examiner, and also to eliminate recitation of one of two recited closed distal ends and eliminate recitation of proximal opening in view of the already recited axial opening. Claims 48, 50 and 60 are amended to recite that no part of the marker extends outside the body. Support is found in the specification and drawings. No new matter is added.

Objection to Claim 46:

Claim 46 is amended to recite a step of providing an introducer, as suggested by the Examiner, for purposes of form, and not with respect to scope of the claim. Withdrawal of the objection is requested.

Double Patenting Rejection:

The Examiner rejects all the pending claims as unpatentable over Claims 1-2 of US 6,228,055. The Examiner's only explanation for this rejection is that according to the Examiner the apparatus of the claims is specific to the method of the application claims, and according to the Examiner, both apparatus and method for marking a particular tissue are specific to each other.

It is respectfully urged that the Examiner's basis for this obviousness type double patenting rejection is unclear. In particular, the Examiner has not provided an explanation as to how granting the

claims would extend a right to exclude, what "specific to each other" means in this context, or how the apparatus and method claims are "specific to each other."

By way of Example, the Examiner is respectfully requested to consider the following differences between Claims 1-2 of US 6228055 and Claim 46. It is respectfully requested that if the Examiner does not withdraw this rejection in the next action, that the Examiner issue a non final action with a more specific explanation of the basis of the double patenting rejection so that Applicant has a full and fair opportunity to respond.

With respect to Claim 1 of the '055 patent and present Claim 46:

Claim 1 recites at least the following not recited in Claim 46 or the other present claims:a deployment actuator with a deployment actuator connector; plus recital of being employed in combination with an instrument that transports a device to a tissue location responsive to position control by a guidance system; plus said medical instrument drawing vacuum to isolate and retain tissue.

On the other hand, Claim 46 recites at least the following not recited in Claim 1: an introducer comprising a tube having a lumen, a closed distal end, a side exit port adjacent the distal end of the tube, and a shaft moveably positioned in the lumen of the tube.

With respect to Claim 2 of the '055 patent and present Claim 46:

Claim 2 recites at least the following not recited in Claim 46 or the other present claims: those items listed above in claim 1; plus a predetermined failure point in the distal region of the deployment actuator connector; plus a member distal region being adapted to function as a forming die, and abutment of a marker element against a stop.

Claim 46 recites at least the following not recited in Claim 2: an introducer comprising a tube having a lumen, a closed distal end, a side exit port adjacent the distal end of the tube, and a shaft moveably positioned in the lumen of the tube.

Claim 47 recites at least the following not recited in Claims 1 or 2: a plurality of marker elements in a lumen, and forcing a second marker element by applying a compressive force to a proximal end of the first marker element.

Claim 48 recites at least the following not recited in Claims 1 or 2: applying a compressive force to a marker element disposed within a marker applier element to force said marker element out a side exit port in the marker element applier. Claim 50 recites applying force to a marker element disposed within an applier to deploy the marker through a side exit port.

Withdrawal of the obviousness type double patent rejection is requested.

102 Rejection:

Claims 48, 50, 51, 54, 58-62, and 65 are rejected as anticipated by Miller et al. (US 5,221,269) This rejection is improper for at least the following reasons.

Independent Claims 48, 50, and 60 have been amended to recite a method wherein no part of the marker element extends outside the body. In contrast, Miller et al. is directed to a wire guide having a portion that extends outside the body to guide the doctor to a lesion site during subsequent surgery (See Abstract and Figure 7 of Miller et al.) It is respectfully urged that Miller et al. does not teach a method of positioning a marker element wherein no part of the marker element extends outside the body. Instead, Miller et al. would appear to desire a guide wire that extends outside the body so that the doctor can follow the guide wire to a lesion site.

Accordingly, withdrawal of the rejection is requested.

103 Rejection:

Claims 46, 47, 49, 52, 53, 55-57, 63, 64, and 67 are rejected as obvious over Miller et al. It is respectfully urged that this rejection is improper for at least the following reasons.

With respect to Claim 46, it is respectfully urged that Miller does not teach or suggest an introducer comprising a tube having a lumen, an axial opening at a proximal end of the tube, a side exit port, and a closed distal end. The Examiner admits that Miller et al. reference does not teach providing the closed distal end, but concludes that it would have been obvious to have provided differences in the specific details of the marker delivery device because, according to the Examiner:

“..either structure satisfies the method of marking the particular structure as claimed by the Applicant.”

It is respectfully urged that this is not a proper basis for rejection. The case law and the MPEP require that the Examiner set forth a prima facie case of obviousness, including showing where in the prior art there is motivation to make the modification suggested by the Examiner.

Assuming for the sake of argument that the Examiner' statement that either structure satisfies the method of marking as claimed by the Applicant is true, it is respectfully urged this alone is not motivation in the prior art for modifying Miller et al. Instead, it is merely improper reliance on the Applicants' disclosure in hindsight to reconstruct the Applicants' invention. It is respectfully urged that the Examiner has not provided any motivation as to why one reading Miller et al. would be motivated to provide a closed distal end in the device of Miller et al.

Further, even if one modified Miller et al. as suggested by the examiner, it is not clear the Miller et al. would teach all the limitations recited in Claim 46. For instance, Claim 46 recites a shaft movable in the lumen, and ejecting at least one marker element from the side exit port into tissue to be marked, wherein the marker element is positioned in said tube distal to said shaft and the marker element is forced out the side exit port by applying compressive force to the proximal end of the shaft.

The Examiner states Miller et al. teaches:

“...plug-drawn force is applied to needle 10 to deliver marker wire 14 to the particular tissue, Fig. 1 and column 4 lines 24-41.”

The Examiner refers to column 4, lines 24-41 which teach Cannula 26 is a thin wall plug drawn stainless steel tube, and that the cannula has a proximal end with a connector hub 28 molded thereabout for ease of handling and for connection to a syringe for injection and irrigation of fluids. It is respectfully urged that this portion of Miller et al. cited by the Examiner does not teach pushing the guide wire 24 with a shaft.

Further, it is respectfully urged that even if Needle 10 were to be considered a shaft, Miller et al. still does not teach or suggest, even when modified as suggested by the Examiner, ejecting a marker element where the marker element is positioned in a tube distal of a shaft, and applying compressive force to the proximal end of the shaft. (See Miller et al's guide wire 14 extending from proximal end of device in Figures 1, 4, and 5 of Miller et al.).

With respect to Claim 47, Claim 47 recites providing plurality of marker elements disposed within the lumen of a marker instrument including a tube, and forcing a second marker out of the side exit port by applying compressive force to a proximal end of a first marker element.

It is respectfully urged that even if the guide wire of Miller et al. is considered a marker element, Miller et al. does not teach multiple marker elements within the lumen of a tube.

Moreover, the Examiner has not provided a prima facie case of obviousness. A prima facie case of obviousness requires motivation in the prior art to make the modification, a likelihood of success, and the modification, if made, must teach all the claim limitations.

There is no motivation to add an additional guide wire to Miller et al., because the guide wire of Miller et al. is to guide the surgeon to an internal lesion. In particular, the Examiner has not shown why one would want more than one guide wire sticking out of the body to guide the surgeon.

Further, if one were to place multiple guide wires into the device of Miller et al., it is respectfully urged that there is no teaching or suggestion as to placing them such that one could force a second marker out by applying compressive force to a first marker. Even if one were to try this, it is not clear that one would succeed, because it is not clear that one guide wire of Miller et al. could be

used to "push" another guide wire of Miller et al. (e.g. what would prevent them from bending or buckling?).

With respect to Claim 49, this rejection is improper for the reason set forth above with respect to claims 48, from which Claim 49 depends. Further, Claim 49 recites applying a compressive force to a second marker element to force a marker element out an exit port. Accordingly, this rejection is improper for the reasons set forth above with respect to Claim 47.

With respect to Claim 55-57 and 65, the Examiner states that the Miller reference does not recite the many available marking agents for marking tissue, but concludes that it would be obvious to provide the claimed marker elements because according to the examiner :

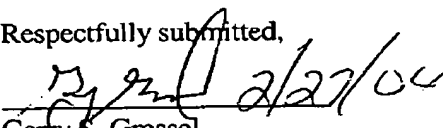
"any available marker agent can be used to satisfy the method as disclosed by the applicant."

It is respectfully urged that this is not a showing of motivation in the prior art, but merely a conclusory statement based on improper hindsight reliance of the Applicant's disclosure.

Conclusion:

The Examiner is respectfully requested to reconsider the application in view of the Remarks above and any amendments. Please call Gerry Gressel at 513 337 3535 with any questions.

Respectfully submitted,


Gerry S. Gressel
Reg. No. 34,342

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(513) 337-3535